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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/719,258 | 12/08/2000 | Friedel Frauendorfer | H01.2-9587 | 7047 |

490 7590 08/01/2005

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| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

DATE MAILED: 08/01/2005

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 09/719,258
Filing Date: December 08, 2000
Appellant(s): FRAUENDORFER, FRIEDEL

Jeremy G. Laabs Reg. No. 53,170
For Appellant

**SUPPLEMENTAL EXAMINER'S ANSWER**

**The Supplement Examiner's Answer of 2/10/05 is hereby vacated.**

This is in response to the appeal brief filed December 1, 2004.

*(1) Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

*(2) Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

*(3) Status of Claims*

The statement of the status of the claims contained in the brief is correct.

*(4) Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

*(5) Summary of Invention*

The summary of invention contained in the brief is correct.

*(6) Issues*

The appellant's statement of the issues in the brief is correct.

*(7) Grouping of Claims*

Appellant's brief includes a statement that claims 1-14 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

*(8) Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

*(9) Prior Art of Record*

| | | |
|---|---|---|
| WO 97/04755 | CADE et al | 2-1997 |
| JP 09-000201 | AKIKUNI et al | 1-1997 |
| US 4,525,306 | YAJIMA et al | 6-1985 |
| EP 0240581 | FLACHER | 10-1987 |
| US 5,948,818 | BUSER et al | 9-1999 |

*(10) Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

**A. Claims 1-9, 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cade et al (WO 97/04755) in view of JP 09-000201 (XP-002143507; hereinafter JP '201) to Akikuni et al or vice-versa.**

JP '201 teaches a gelatin capsule containing a water-in-oil emulsions of perilla oil, perilla extract, polyglycerol fatty acid ester, and monoglycerol fatty acid ester. The exemplary gelatin capsule contains 150mg of alpha-linolenic acid. The reference discloses that fats and oils, which contain omega-3-polyenoic fatty acid (polyunsaturated fatty acids), and perilla treat inflammatory bowel disease (IBD). The fats and oils utilized preferably contain alpha-linolenic acid, eicosapentaenoic acid, or docosahexaenoic acid. See abstract. The omega-3-polyunsaturated fatty acids may be obtained from fish oil or sesame oil. See page 1 of translated document.

The examiner relies on Cade et al to teach a xylose hardened gelatin capsule since JP '201 does not specify the composition of the gelatin capsule. Cade et al teach a hard gelatin with reduced water transport or water vapor permeation by either laminating a polymer layer onto the

gelatin shell or adding an additive to the gelatin formulation. Additives such as instant xylose, which are added to the gelatin solution, are taught to reduce water permeability and hygroscopicity (pg. 7). Cade teaches capsules with low permeability to water vapor, reduce sensitivity to storage conditions and improve the protection of the compositions contained within (pg. 1, first paragraph) since permeation by the environment may cause the composition within to agglomerate or degrade chemically (pg. 2, second and fourth paragraph). The concentration of the additives is in the range of 1-50%. See page 8, lines 1-5. The rupture times for various additives are taught in Table 9. Lastly the capsule can be used as a container for nutrients, medicaments, etc. (page 10). Cade et al teach the capsules may provide a container for nutrients, medicaments, hygroscopic materials, etc. Additionally, the capsule may contain special forms such as microdispersions, controlled-release substances, etc.. See page 10, lines 18 to page 11, line 5.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Cade et al and JP '201. A skilled artisan would have been motivated to harden a gelatin capsule with xylose since Cade et al teaches that additives such as xylose reduce the permeability of the capsule by the environment, which chemically degrade the capsule fill. Therefore, a skilled artisan would have been motivated to harden the gelatin capsule of JP '201 with xylose to prevent the degradation of the polyunsaturated fatty acids contained within.

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings of JP '201 and incorporate JP's fatty acids into Cade's xylose hardened gelatin capsule. A skilled artisan would have been motivated to do so

since JP teaches the use of the polyunsaturated fatty acids to treat inflammatory bowel disease. Therefore, a skilled artisan would have been motivated to utilize instant polyunsaturated fatty acids to treat IBD (inflammatory bowel disease). Furthermore, a skilled artisan would reasonably expect success since Cade et al teach the use of the xylose hardened gelatin capsules as a container for nutrients, medicaments, and materials that are hygroscopic.

It is the examiner's position that the prevention of the chemical degradation of the capsule fill taught by Cade et al would read on applicant's recitation of inhibiting peroxidation of the fatty acids since Cade et al teach the use of sugar additives, i.e. xylose, to prevent permeation of the environment into the capsule. Therefore, it is implicit that Cade et al's xylose hardened gelatin capsule would reduce oxidation of the fatty acids contained within since the capsule protects the fill from environmental factors including oxygen.

Lastly with regard to claims 12-14, the examiner points out that these claims are product by process claims. However, according to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

***(11) Response to Argument***

Appellant argues that neither Cade nor JP teaches or suggests a gelatin capsule that is xylose-hardened to inhibit the peroxidation of polyunsaturated fatty acids. Appellant argues that neither references mention peroxidation. Thus, the Appellant argues there is no motivation to

combine the references. Appellant argues that Cade is only concerned with water transport and hygroscopicity and not instant peroxidation, thus there is no motivation to look at this reference. Appellant argues that Cade et al is directed to preventing moisture permeation of the capsule and this is not equivalent to preventing peroxidation.

Firstly, with regard to the argument that the prior art is concerned with different problems then the inventive problem, i.e. Cade is interested in water vapor permeation and instant invention is interested in peroxidation, the examiner respectfully points out that the use of patents as references are not limited to what the patentees describe as their own inventions or the problems with which there are concerned. They are part of literature of the art, relevant for all they contain." *In re Heck*, 699 F2d 1331, 1332-33 216 USPQ 1038, 1039.

Secondly, the examiner respectfully points out that the prior art does not have to explicitly list all the properties that naturally flow from the teachings of the prior art. In instant case, although Cade et al do not explicitly teach the inhibition of peroxidation, it is the examiner's position that this is implicit in Cade's teachings. Cade teaches a hard gelatin capsule with low reduced water vapor permeation though the capsule. On page 1, Cade discloses that the capsules improve storage conditions by improving the protection of fills from atmospheric water vapor. Additionally on page 6, Cadet discloses that the addition of a polyols such as sugars including instant xylose, sugar alcohols, and polyvinyl alcohols significantly reduce water vapor permeability.

Clearly it is implicit that the preventing water vapor from entering the capsule, oxidation of the fill would be reduced. Peroxidation is the process of oxidizing (the addition of oxygen); therefore by preventing vapor from entering the capsule, the amount of oxygen entering the

capsule is reduced. It should be further noted that appellant merely recites "inhibit peroxidation", however the claims do not recite by *how much* peroxidation is inhibited. Thus, it is the examiner's position that reduction of oxidation of the capsule fill reads on the broad recitation of "inhibition" without a degree of inhibition. Moreover, the examiner is not equating that peroxidation occurs solely due to humidity rather the examiner is pointing out that oxidative conditions include both exposure to air and moisture. The examiner also notes that in the instant specification, the appellant prevents the polyunsaturated fatty acids contained in the capsule from "going bad" by hardening the capsule with xylose. The examiner respectfully points out that Cade et al *also* is preventing degradation of the capsule fill by hardening the capsule with an additive, such as instant xylose.

Lastly, the examiner points out that Cade teaches the additive in an amount of 1-50% to harden the gelatin capsule. Appellant's specification, on page 5 states that xylose hardening for the invention is done according to EP 0240581, especially example 3. EP '581 teaches xylose in the amount of 2% to harden the gelatin capsule. It should further be noted that the only reference to the amount that is "sufficient" in inhibiting peroxidation in the specification is page 5. Thus, it can be clearly seen that since Cade et al teach the same amount as appellant and appellant clearly states this amount provides sufficient hardening to prevent oxidation, Cade's xylose hardened gelatin capsule would implicitly inhibit peroxidation of the fill contained within. Furthermore, the applicant argues that Cade's xylose hardened gelatin capsule does not prevent inhibition but does not structurally distinguish Cade's capsules from the inventive capsules. It is the examiner's position that the prior art teaches the same capsule since the prior art not only utilizes xylose to harden the gelatin capsules but also teaches the same amount for the same purpose, i.e. the

pharmaceutical industry. Again, the examiner respectfully reiterates that the prior art does not have to recognize every property that naturally flows from the a device or utilize the same language as applicant to achieve a methodology, i.e. inhibiting peroxidation versus inhibiting water vapor permeability and environmental exposure (see page 2).

Appellant argues that the examiner has used hindsight in structuring of the rejections and arguments.

The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In instant case, JP teaches a gelatin capsule containing unsaturated fatty acids. Cade et al teach an improved gelatin capsule that is hardened by additives such as instant xylose, to prevent degradation of the material contained within. Cade recognizes the wide use of gelatin capsules in the pharmaceutical industry (see page 1) and teaches an improved capsule. Therefore, a skilled artisan would have been motivated to look to Cade's improved gelatin capsules and utilize the xylose-hardened capsules to prevent degradation of the material contained within. The improvement of a prior art device is sufficient motivation to utilize the said device.

Conversely, Cade et al provide a motivation to utilize Yajima's polyunsaturated fatty acids since Cade et al clearly state that the xylose hardened gelatin capsule is utilized as a

container for nutrients and medicaments and recognizes the wide use of gelatin capsules in the pharmaceutical industry.

Appellant argues that a showing of unexpected properties overcomes a prima facie obviousness case. Appellant argues that the application provides examples of unexpected results demonstrating the peroxidation of fatty acids in a gelatin capsule compared to the peroxidation of fatty acids in a xylose-hardened capsule.

Firstly, it is pointed out that this is the first time appellant has mentioned unexpected results to support appellant's arguments of unobviousness.

Secondly, it is respectfully pointed out that unexpected results should compare the closest prior art. See *In re* Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In instant case applicant has not compared the closest prior art with the instant invention. Appellant asserts that Cade et al's xylose-hardened gelatin capsules do not prevent peroxidation, however appellant has not submitted evidence demonstrating this. Therefore, it is respectfully pointed out that unexpected results must be a comparison of Cade's xylose hardened capsules and instant xylose-hardened capsules since the appellant has not structurally distinguished the instant invention over the prior art.

Appellant argues that neither Cade nor JP teach a retarded release time of more than 45 minutes. Appellant argues that Cade teaches that the dissolving time decreases with increasing content of the additive. Thus, appellant argues that Cade teaches away from the instant claims.

The examiner does agree that Cade teaches an increased amount of an additive will decrease the rupture time, however Cade teaches the minimal amount of the additive that does not decrease rupture time and the maximum amount of the additive that does decrease rupture

time. Moreover, the examiner points out that the claims merely state that the capsule has a "retarded release of no more than 45 minutes." Firstly, it is respectfully submitted that the claims are given their broadest reasonable interpretation. *In re Hyatt*, 211 F.3d 1367, 54 USPQ2d 1664, 1667. Therefore, since appellant only defines the retarded release as it cannot be *more* than 45 minutes and does not define retarded release in specific parameters with regards to when it can release to be defined as "retarded release"; a release after two minutes can be interpreted as retarded release. Thus, although Table 9 demonstrates that the rupture time is a function of concentration of the additive, it also demonstrates that for instance, a 10% concentration has a release at approximately 2 minutes. Therefore, a rupture of two minutes, which is not an immediate release fulfills the requirement that A) the release is not more than 45 minutes and B) that capsule has retarded release.

Secondly, it is the examiner's position that Cade et al's capsule would implicitly be released within applicant's scope since Cade et al teach the same concentration of xylose as applicant. Thus the time of release would have to be that of appellant's since the appellant's capsule is the same as the instant invention's capsule.

Appellant argues that neither reference suggests the explicit intention of excluding an antioxidant.

The examiner points out that neither Cade et al nor JP teach the use of an antioxidant in the formulation; thus, this in itself reads on claim 6, wherein the limitation requires the exclusion of an antioxidant. Therefore, it is respectfully submitted that a prior art does not have to state the reasons components are excluded, the fact that the component is excluded demonstrates that the component is not critical to the invention. .

**B. Claims 1-5, 7, and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yajima (4,525,306) in view of Cade et al (WO 97/04755) or vice-versa. The rejection of claim 6 has been withdrawn.**

Yajima teaches the prevention of oxidation of oils and fats, and soft gelatin capsules containing the fats and oils. The reference discloses that the prevention of the oxidation of oils and fats is accomplished by physical means such as keeping oils and fats away from oxygen, storing them at low temperatures, and adding antioxidants. See column 1, lines 5-20. Yajima teaches that although it is desirable from a nutritional point to ingest these fats and oils, fats and oils increase in their vulnerability to oxidation as the constituent fatty acids increase in the degree of unsaturation. It is taught that fish oil contains high contents of eicosapentaenoic acid and unsaturated fatty acids and is effective for the prevention of thrombi and the hardening of arteries. Additionally, Yajima et al teach the use of essential fatty acids for nutritional purposes. See column 2, lines 4-35. Yajima teaches the use of the invention for all fats and oils that are exposed to oxidative conditions. See column 2, lines 49-52.

The examiner relies on Cade et al to teach a xylose hardened gelatin capsule since Yakima et al '201 does not specify the gelatin capsule composition utilized. Cade et al teach a hard gelatin with reduced water transport or water vapor permeation by either laminating a polymer layer onto the gelatin shell or adding an additive to the gelatin formulation. Additives such as instant xylose, which are added to the gelatin solution, are taught to reduce water permeability and hygroscopicity (pg. 7). Cade teaches capsules with low permeability to water vapor, reduce sensitivity to storage conditions and improve the protection of the compositions contained within (pg. 1, first paragraph) since permeation by the environment may cause the

composition within to agglomerate or degrade chemically (pg. 2, second and fourth paragraph). The concentration of the additives is in the range of 1-50%. See page 8, lines 1-5. The rupture times for various additives are taught in Table 9. Lastly the capsule can be used as a container for nutrients, medicaments, etc. (page 10). Cade et al teach the capsules may provide a container for nutrients, medicaments, hygroscopic materials, etc. Additionally, the capsule may contain special forms such as microdispersions, controlled-release substances, etc.. See page 10, lines 18 to page 11, line 5.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Yajima et al and Cade et al. A skilled artisan would have been motivated to harden Yajima's gelatin capsule with xylose since Cade et al teach this reduces the permeability of the capsule by the environment, which chemically degrades the capsule fill. Therefore, a skilled artisan would have been motivated to harden the gelatin capsule of Yajima et al with xylose to prevent the degradation of the fatty acids contained within. Moreover since Yajima recognizes the instability of unsaturated fatty acids in the presence of oxidative conditions, a skilled artisan would have been further motivated to look to Cade who teaches xylose harden capsules that prevent permeation of the environment.

Alternatively, a skilled artisan would have been motivated to combine Cade et al and Yajima et al and include fatty acids into the gelatin capsule of Cade et al. A skilled artisan would have been motivated to select the Yajima's unsaturated fatty acids for incorporation into Cade's capsules to prevent thrombi and for their nutritional value.

It is the examiner's position that the prevention of the chemical degradation of the capsule fill taught by Cade et al would read on appellant's recitation of inhibiting peroxidation of

the fatty acids since Cade et al teach the use of sugar additives, i.e. xylose, to prevent permeation of the environment into the capsule. Therefore, it is implicit that Cade et al's xylose hardened gelatin capsule would reduce oxidation of the fatty acids contained within since the capsule protects the fill from environmental factors including oxygen.

Lastly with regard to claims 12-14, the examiner points out that these claims are product by process claims. However, according to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

***(11) Response to Argument***

Appellant's argues Yajima teaches the use of antioxidants to prevent the peroxidation of the fatty acids and oil and thus teaches away from the instant invention since instant invention does not require antioxidants. Appellant points out that page 5 of the instant invention states that antioxidants are not needed. It is further argued that since Yajima et al solves the problem of oxidation using chemical additives, there is no motivation to look elsewhere.

Firstly, it is respectfully pointed out that appellant's claim language does not exclude the presence of an antioxidant. Thus, the appellant relies on certain features that are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Secondly, the examiner recognizes that Yajima et al attempt to solve the problem of oxidation with the use of antioxidants. However, it is also pointed out that Yajima recognizes the vulnerability of fats and oil, especially unsaturated fatty acids, to oxidative conditions and also recognizes that antioxidants are not always effective. See column 1, lines 44-65. Both the references are directed to the same goal, i.e. to protect the capsule fill. Cade et al teach the use of a xylose hardened gelatin capsule to protect the capsule fill form humidity and moisture permeation and Yajima et al teach the use of a gelatin capsule. Thus, a skilled artisan would have been motivated to look outside of Yajima et al and also utilize Cade et al's method to provide for an additive effect of preventing peroxidation of the fill contained within the capsule.

Moreover, it is respectfully pointed out that the rejection is also Cade et al in view of Yajima et al. Cade et al teach the use of the xylose-hardened gelatin capsule for medicaments and nutrients. Yajima et al teach the use of the instant essential fatty acids for not only for their nutritional purposes but also for their treatment of heart disease. Thus, a skilled artisan would have been motivated to utilize Yajima's unsaturated fatty acids in Cade's capsules to treat thrombi and provide nutritional benefits.

Appellant argues that Cade et al do not address peroxidation. Appellant argues that Cade is only concerned with water transport and hygroscopicity. Appellant argues that Cade et al is directed to preventing moisture permeation of the capsule and this is not equivalent to preventing peroxidation.

Firstly, the examiner respectfully points out that the prior art does not have to explicitly list all the properties that naturally flow from the teachings of the prior art. In instant case, although Cade et al do not explicitly teach the inhibition of peroxidation, it is the examiner's

position that this is implicit in Cade's teachings. Cade teaches a hard gelatin capsule with low reduced water vapor permeation through the capsule. On page 1, Cade discloses that the capsules improve storage conditions by improving the protection of fills from atmospheric water vapor. Additionally on page 6, Cadet discloses that the addition of a polyols such as sugars including instant xylose, sugar alcohols, and polyvinyl alcohols significantly reduce water vapor permeability.

Clearly it is implicit that the preventing water vapor from entering the capsule, oxidation of the fill would be reduced. Peroxidation is the process of oxidizing (the addition of oxygen); therefore by preventing vapor (a liquid suspended in air) from entering the capsule, the amount of oxygen entering the capsule is reduced. It should be further noted that appellant merely recites "inhibit peroxidation", however the claims do not recite by *how much* peroxidation is inhibited. Thus, it is the examiner's position that reduction of oxidation of the capsule fill reads on the broad recitation of "inhibition" without reciting the degree of inhibition. Moreover, the examiner is not equating that peroxidation occurs solely due to humidity, rather the examiner is pointing out that oxidative conditions include both exposure to air and moisture. The examiner also notes that in the instant specification, the applicant prevents the polyunsaturated fatty acids contained in the capsule from "going bad" by hardening the capsule with xylose. The examiner respectfully points out that Cade et al also is preventing degradation of the capsule fill by hardening the capsule with an additive, such as instant xylose.

Lastly, the examiner points out that Cade teaches the additive in an amount of 1-50% to harden the gelatin capsule. Appellant's specification, on page 5 states that xylose hardening for the invention is done according to EP 0240581, especially example 3. EP '581 teaches xylose in

the amount of 2% to harden the gelatin capsule. It should further be noted that the only reference to the amount that is "sufficient" in inhibiting peroxidation in the specification is page 5. Thus, it can be clearly seen that since Cade et al teach the same amount as appellant and appellant clearly states this amount provides sufficient hardening to prevent oxidation, Cade's xylose hardened gelatin capsule would implicitly inhibit peroxidation of the fill contained within. Furthermore, the appellant argues that Cade's xylose hardened gelatin capsule does not prevent inhibition and the instant invention is structurally distinguishable from Cade's capsules. It is the examiner's position that the prior art teaches the same capsule shell since the prior art not only utilizes xylose to harden the gelatin capsules but also teaches the same amount for the same purpose, i.e. the pharmaceutical industry. Again, the examiner respectfully reiterates that the prior art does not have to recognize every property that naturally flows from the a device or utilize the same language as applicant to achieve a methodology, i.e. inhibiting peroxidation versus inhibiting water vapor permeability and environmental exposure (see page 2).

Appellant argues that the examiner has used hindsight in structuring of the rejections and arguments.

The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In instant case, Cade et al provide a motivation to utilize Yajima's polyunsaturated fatty acids since Cade et al clearly state that the xylose hardened gelatin capsule is utilized as a container for nutrients and medicaments and recognizes the wide use of gelatin capsules in the pharmaceutical industry.

With regard to Yajima et al, not only does the ordinary artisan recognize the vulnerability of fatty acids to oxidizing conditions but Yajima also teaches this. Further, although Yajima utilizes antioxidants, Yajima also recognizes that antioxidants are not always effective, thus providing need to look outside the reference and supplement Yajima's method of protecting the fatty acids from oxidizing conditions with Cade's teachings for an additive effect of protecting the capsule fill.

Appellant argues that a showing of unexpected properties overcomes a prima facie obviousness case. Appellant argues that the application provides examples of unexpected results demonstrating the peroxidation of fatty acids in a gelatin capsule compared to the peroxidation of fatty acids in a xylose-hardened capsule.

Firstly, it is pointed out that this is the first time appellant has mentioned unexpected results to support appellant's arguments of unobviousness.

Secondly, it is respectfully pointed out that unexpected results should compare the closest prior art. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In instant case appellant has not compared the closest prior art with the instant invention. Appellant's asserts that Cade et al's xylose-hardened gelatin capsules do not prevent peroxidation, however applicant has not submitted evidence demonstrating this. Therefore, it is respectfully pointed out that unexpected results must be a comparison of Cade's xylose hardened capsules and instant xylose-hardened

capsules since the appellant has not structurally distinguished the instant invention over the prior art.

Appellant argues that neither Cade nor Yajima teach a retarded release time of more than 45 minutes. Appellant argues that Cade teaches that the dissolving time decreases with increasing content of the additive. Thus, appellant argues that Cade teaches away from the instant claims.

The examiner does agree that Cade teaches an increased amount of an additive will decrease the rupture time, however Cade teaches the minimal amount of the additive that does not decrease rupture time and the maximum amount of the additive that does decrease rupture time. Moreover, the examiner points out that the claims merely state that the capsule has a "retarded release of no more than 45 minutes." Firstly, it is respectfully submitted that the claims are given their broadest reasonable interpretation. *In re Hyatt*, 211 F.3d 1367, 54 USPQ2d 1664, 1667. Therefore, since appellant only defines the retarded release as it cannot be *more* than 45 minutes and does not define retarded release in specific parameters with regard to when it can release to be defined as "retarded release"; a release after two minutes can be interpreted as retarded release. Thus, although Table 9 demonstrates that the rupture time is a function of concentration of the additive, it also demonstrates that for instance, a 10% concentration has a release at approximately 2 minutes. Therefore, a rupture of two minutes, which is not an immediate release, fulfills the requirement that A) the release is not more than 45 minutes and B) that capsule has retarded release.

Secondly, it is the examiner's position that Cade et al's capsule would implicitly be released within appellant's scope since Cade et al teach the same concentration of xylose as

applicant. Thus the time of release would have to be that of appellant's since the appellant's capsule is the same as the instant invention's capsule.

Appellant argues that the references do not teach the exclusion of antioxidants since Yajima et al teach antioxidants to protect the capsule fill.

The examiner notes Yajima's teachings of antioxidants to protect the capsules fill and has withdrawn the rejection over claim 6.

Appellant argues that Yajima discloses that the fatty acids are effective in treating heart disease. Appellant argues that Yajima does not disclose the use of the fatty acids for treating intestinal inflammation and metabolism of fat.

The examiner respectfully points out that the appellant is claiming a *product* containing fatty acids in a xylose-hardened gelatin capsule and not a *method* of treatment. It is respectfully submitted that the appellant is claiming the intended use of the dosage form rather than a structural limitation on the product itself. Therefore, since the intended use of the claimed invention does not result in a structural difference between the claimed invention and the prior art, it does not patentably distinguish the claimed invention from the prior art and is not given patentable weight. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Appellant argues that claimed process claims of 12-14 have not been considered.

The examiner respectfully points out that the instant claims are product-by-process claims wherein patentability of the claims is based on the product itself and not the process in which it is made. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Moreover the appellant has not provided any evidence indicating that a different product is

obtained by the instant process of claims 12-14. Thus, the product-by-process claims are not given patentable weight.

**C. NEW GROUNDS OF REJECTION (37 CFR § 41.39(a)(2))**

**Claims 1-5 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0240581 to Flacher in view of Buser et al (US 5,948,818) or vice-versa.**

EP '581 teaches a gelatin capsule with controlled active release and the process for producing the gelatin capsule. EP '581 recognizes that it is desirable that many pharmaceutical actives release at a specific time or until they have reached the small intestine. See page 2 of translated document. Flacher discusses several methods in the prior art that attempt to provide delayed release including lacquering and coating processes wherein polymers that do not dissolve below a pH of 5 or 5.5 are layered onto the dosage form. However, Flacher discloses that these techniques are time and equipment intensive. See page 3 of translated document. Thus, EP '581 teaches a method of hardening gelatin capsules with a simple process wherein 0.001-10%, such as instant xylose, are added to the capsule solution. See page 4. Example 3 discloses 2 parts xylose is added to 100 parts gelatin. Flacher teaches the process of making the inventive xylose-hardened capsule does not require organic solvents and thus is safe with regard to the environment. See page 6. Example 4 discloses that the capsule does not release in artificial gastric fluid for two hours and release within half-hour after being exposed to intestinal fluid.

EP '581 does not teach the use of instant polyunsaturated fatty acids.

Buser et al teach the treatment of inflammatory bowel diseases using an oral dosage form containing omega-3-polyunsaturated fatty acids. See abstract. The source of the unsaturated fatty acids is fish oil. See column 3, lines 34-35. Buser et al teach that it has been found that the

optimum combination of absorption and the absence of side effects occur if the release of the polyunsaturated fatty acids is controlled to occur in the ileum. See column 3, lines 15-20. Buser teaches the oral dosage form is preferably a coated capsule, especially a hard gelatin capsule. The criticality of the coating is that it must release in the acid of the ileum and a coating that is resistant for a period of 30 to 60 minutes at pH 5.5. Buser teaches a polymer coating for the oral dosage form. See column 3, lines 45-30.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of EP '581 and Buser et al and incorporate Buser's unsaturated fatty acids into EP's xylose hardened gelatin capsules. One would have been motivated to do so since Buser teaches polyunsaturated fatty acids are effective in treating inflammatory bowel disease. Therefore, a skilled artisan have been motivated to utilize the instant unsaturated fatty acids to treat inflammatory bowel disease. Further, Buser teaches the efficacy of these fatty acids is optimum if the fatty acids have controlled release in the ileum. Therefore, one would have expected similar results since EP '581 teaches a controlled release gelatin capsule that meets the criteria of resistant for a period of 30 to 60 minutes at pH 5.5 and releases in the intestine.

Conversely, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Buser et al and EP '581 and utilize EP's xylose hardened capsules for Buser's fatty acids. One would have been motivated to do so since EP '581 teaches an improved controlled release capsule that is simple, cost-effective, and environmentally and physiologically safe over the prior art controlled release gelatin capsules. Further, EP '581 teachings the xylose-hardened capsules are an improvement of polymer coated

capsules, i.e. those that are taught and preferred by Buser et al. Therefore, a skilled artisan would have been motivated to utilize EP '581 improved controlled release gelatin capsule that is xylose-hardened over the prior art's controlled release gelatin.

With regard to the recitation "to extent sufficient to inhibit peroxidation", it is the examiner's position that EP '581 meets this recitation since the prior art capsule and inventive capsule are structurally the same as stated by applicant's specification on page 5.

With regard to the product-by-process claims, the patentability of the claims is based on the product itself and not the process in which it is made. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

***(11) Response to Argument***

Appellant argues that neither EP 0240581 (Flacher) nor US 5948818 (Buser) teach a gelatine capsule that is xylose hardened sufficient to inhibit peroxidation of polyunsaturated fatty acids. Appellant argues that Flacher does not teach the use of polyunsaturated fatty acids or the peroxidation of these fatty acids. Appellant argues that Buser teaches the use of polyunsaturated fatty acids and the problem of polyunsaturated fatty acids but solves the problem by utilizing chemical antioxidants. Lastly, appellant argues that the examiner has not proved that Flacher's gelatin capsule is capable of inhibiting the peroxidation of fatty acids nor has the examiner provided any evidence that this is inherent.

Firstly, the examiner acknowledges that Flacher does not teach the use of the instant fatty acids in the xylose-hardened capsules. However, it is respectfully pointed out that the claims are rejected under obviousness and thus the examiner relies on the secondary reference to cure the deficiency of the primary reference.

Flacher teaches the instant xylose-hardened capsule for controlled release of an active at a specific time or until the active reaches the small intestine. Flacher states that many known pharmaceutical products require targeted release or release in the small intestine. See page 1. Thus, this is a implicit suggestion that a skilled artisan may put any active ingredient requiring controlled or targeted release in Flacher's capsules. Flacher further states the prior art methods of lacquering gelatine capsules with coatings such as polymers or formaldehydes are either complex or toxic; Flacher discloses that the instant xylose hardened gelatine capsules are simple and non-toxic. See page 4, second paragraph.

Therefore, it is clear that Flacher provides the suggestion to utilize an active ingredient that requires target controlled release and the motivation to utilize the instant capsule over the prior art capsules.

Buser teaches that the instant polyunsaturated fatty acids provide treatment for inflammatory bowel disease. Moreover, Buser clearly states the instant fatty acids have optimum absorption if the release is controlled to occur in the ileum (the lower division of the small intestine). See column 3, lines 15-20. Buser further teaches this controlled release of the instant fatty acids reduce the side effects associated with the polyunsaturated fatty acids. Buser suggests the use of a coated capsule, for instance a soft or preferably a hard gelatine capsule, such that the coating provides for the targeted release. A polymer coating on the gelatine capsule provides this targeted release. See column 3, lines 41-50.

Thus, essentially Buser teaches a polymer hardened gelatine capsule to release the instant fatty acids in a controlled manner to treat inflammatory disease.

Therefore, it is the examiner's position that there is a clear motivation to utilize the instant fatty acids in Flacher's capsules, i.e. to treat inflammatory bowel disease. Firstly, the selection of an active agent depends on the type of disease to be treated. Secondly, Flacher's only criteria for the active to be suitable for the xylose-hardened capsule, is that the active ingredient must require controlled release in the lower intestine. Thus, a skilled artisan would reasonably expect success by the combination since the instant fatty acids require a capsule that provides controlled release in the small intestine, and Flacher's xylose hardened capsule does. Moreover, one would have been motivated to utilize Flacher's xylose hardened capsules versus Buser's polymer hardened gelatine capsule since Flacher teaches the process of making the instant xylose gelatine capsule is simpler and safer compared to the prior art's.

With the regard to the question of whether the prior art teaches the problem of peroxidation, it is respectfully pointed out that the claims rejected by the instant rejection are directed to the *product*, i.e. independent claim 1 and those claims depending from claim 1, and not the *method*, i.e. independent claim 11. This is a critical aspect since the examiner's rejection is based on the fact that the product is prima facie obvious. Therefore, the fact that applicant has recognized another advantage, i.e. that Flacher's capsules reduces peroxidation of polyunsaturated fatty acids, would flow naturally from following the suggestion of the prior art and thus cannot be the basis for patentability since the differences are obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Lastly with regard to appellant's argument that the examiner has not provided any evidence that Flacher's capsule will inherently inhibit peroxidation, the examiner first points out that independent claim 1 requires that the capsule is hardened with xylose "to an extent the

inhibits peroxidation. The specification directly states that EP 0240581, example 3, teaches the instant xylose-hardened capsule to achieve said purpose of inhibiting peroxidation. See page 5 of the instant specification. Nowhere does the specification teach how much xylose is needed to harden the capsule to achieve said purpose, other than EP's disclosure. Thus, the examiner is not utilizing the applicant's own disclosure to construct the rejection, as argued by the appellant. The examiner is merely using applicant's own admission of prior art since it is quite clear that the "xylose hardened capsule" is not a novel capsule and it was in the public's domain before the instant invention was made. Further, a discovery of an inherent element found in the prior art product, does not patentably distinguish the invention from the prior art.

Therefore, it is respectfully submitted that the instant *product* is prima facie obvious over the prior art *product*.

Appellant argues that the references do not teach the exclusion of antioxidants since Yajima et al teach antioxidants to protect the capsule fill.

The examiner notes Buser's teachings of antioxidants and has withdrawn the rejection over claim 6. The examiner also notes that dependent claim 7 depends on independent claim 11, which has not been rejected; thus the rejection of claim 7 has been withdrawn.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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July 25, 2005

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